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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,538

02/03/2005

Kenji Sunagawa

KUP-6

7543

20808

7590

06/03/2009

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,538	<b>Applicant(s)</b> SUNAGAWA, KENJI	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/17/2009 has been entered.

### ***Drawings***

2. The drawings are objected to because, in Figures 1, 3-5, and 8, the unlabeled rectangular boxes shown in the drawings should be provided with descriptive text labels. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (US 3,943,936, hereinafter “Rasor”) in view of Heller (US 6,294,281, hereinafter “Heller”). Rasor discloses the essential features of the claimed invention, including a pacemaker capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 5A-5C and 9) having a control unit (30), a heart stimulating means (output of 30), an electrocardiograph information detecting means (“trigger input” and col. 11, lines 8-13), and a fuel cell power unit (col. 3, lines 19-21), wherein the control unit outputs the control signal based on the ECG information (col. 11, lines 8-13). Further, Rasor discloses that the control unit comprises a stimulation timing determining means (“pulse forming circuit”) that decides the timing of pulses and a stimulation timing changing means (col. 11, lines 15-18) that changes the timing of stimulation when certain conditions are met. Rasor does not disclose that the fuel cell is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators and

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oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution. Heller teaches a biological fuel cell for use with implantable devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein the anode is coated with immobile layer of mediators (redox polymer layer; cols. 5-9) and oxidative enzymes for biological fuels (cols. 9-12), wherein the layer prevents oxygen existing in a biological body from contacting the anode (col. 8, line 16; "poly(acrylic) acid"), and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions (col. 13, lines 21-47 and col. 14, lines 4-18); wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid (col. 14, lines 35-43); and wherein the anode and cathode contact the electrolyte solution (col. 14, lines 35-43) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rasor's invention by providing a biological fuel cell for use with implantable devices that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode; wherein

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the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Please note that Heller's coating material (poly(acrylic) acid) inherently prevents oxygen existing in a biological body from contacting the anode. See Reichert et al. (US 5,270,128; col. 3, lines 40-65) as evidence of inherency. In the alternative, it is notorious in the fuel cell arts to prevent oxygen from contacting anodes to provide the predictable result of avoiding degradation of the anode material.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by preventing oxygen from contacting the anode to provide the predictable result of avoiding degradation of the anode material.

5. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor in view of Heller and Fujii et al. (US 5,411,535, hereinafter "Fujii"). Rasor's modified invention (as applied to claim 10) discloses the essential features of the claimed invention except for a transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control

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unit. Fujii teaches an implantable pacemaker, similar to the one taught by Rasor, with transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit (Fig. 7) to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by providing transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body.

### ***Response to Arguments***

6. Applicant's arguments filed 4/17/2009 have been fully considered but they are not persuasive. Applicant argued that Rasor fails to disclose a stimulation timing changing means that changes the timing of stimulation to generate control signals, where the control unit changes the stimulation timing when certain conditions are fulfilled. As a threshold matter, it is noted that there is no link between the signals utilized in these two steps. In other words, the "certain conditions" are not based on the control signals or any other signals or conditions set forth in the claim. Likewise, Applicant's discussion of changing stimulation timing based on information sent from outside, etc. is not claimed in claim 10, and is addressed as an obvious modification with regards to claims 11-13. The Examiner maintains that Rasor discloses a

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stimulation timing changing means that changes the timing of stimulation to generate control signals, where the control unit changes the stimulation timing when certain conditions are fulfilled at column 11, lines 15-18. This passage describes demand pacing, which provides a pulse when no intrinsic (sinus) pulse is present and provides no pulse when a sinus pulse is present. This presence of a sinus pulse corresponds to the claimed "certain conditions," and a stimulation timing changing means (circuitry within the device) detects this condition, either provides a pulse or refrains from doing so (i.e., "suppress the trigger signal" as disclosed by Rasor), and this provision or suppression of a pulse "changes the stimulation timing." As such, Rasor provides a stimulation timing changing means that changes the timing of stimulation to generate control signals, where the control unit changes the stimulation timing when certain conditions are fulfilled, as claimed.

7. Applicant further argued that Rasor and Heller are lacking teachings of the claimed anode and cathode coatings. However, these teachings are provided and described above, as well as in the previous Office Action.

8. Applicant further argued that the fuel cell of Heller was not designed with safety considerations in mind because of disclosure of certain embodiments containing allegedly toxic compounds and the need for a relatively large waste container. However, it is respectfully submitted that (1) Applicant has provided no evidence that such compounds are in fact toxic, (2) these compounds are disclosed as used in "an alternative embodiment" (col. 6, lines 46-54) and thus do not negate or obviate disclosure of other embodiments *not* containing these compounds, and (3) these



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compounds are bound to a polymer redox layer that would prohibit the compounds from freely circulating in the blood and manifesting toxic reactions. Further, the Examiner was unable to find disclosure of the alleged requirement that Heller's invention requires a waste container, and even if such requirement is present (which the Examiner does not concede), the prohibition of a waste container is not present in the claims. Lastly and most importantly, Heller's invention is clearly designed with safety and biocompatibility issues in mind because of the explicit disclosure that "[the] fuel cell can be implanted in a portion of the animal or plant where a fluid, such as blood or sap, flows" (col. 2, lines 53-55), and that the "fuel cell may be configured for implantation into a person or animal to operate an electrical device, such as a pacemaker" (col. 2, lines 63-65). This clearly indicates that Heller designed and envisioned the fuel cell to be used both within the human body and with a device similar to Rasor's.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/  
Examiner, Art Unit 3762